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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 09/557,955
Filing Date: April 25, 2000
Appellant(s): PENFOLD ET AL.

Marina T. Larson
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed June 1, 2004.

(1) Real Party in Interest

A statement identifying the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

A statement identifying the related appeals and interferences which will directly affect or be directly affected by or have a bearing on the decision in the pending appeal is contained in the brief.

(3) Status of Claims

The statement of the status of the claims contained in the brief is correct.

(4) Status of Amendments After Final

The Appellant's statement of the status of amendments after final rejection contained in the brief is correct. Appellants take issue with the non-entry of the after finals. The after final amendments were properly not entered. In the second after final amendment presented concurrently with the first brief, Appellant chose to use terms that lacked antecedent basis in the specification and chose to merely assert that it was merely a grammatical error. Appellant's after final failed to particularly point to the specification for support for the proposed amendment and failed to provide any rationale as to how the language derived from the cited passage. No new issues are permitted After Final or at Appeal, Appellants are directed to 37 CFR 1.116 and 37 CFR 1.195. Further, proper procedure for objecting to the non-entry of an After Final response is a petition pursuant to 37 CFR 1.181 and not the filing of an Appeal Brief. The claims as currently drafted do not defy interpretation and the alleged grammatical error in Appellants drafting of the claim does not speak to the merits of the rejections of record. Prosecution will not be reopened.

(5) Summary of Invention

The summary of invention contained in the brief is deficient because the claims are directed to a device *per se* and not a method of "using".

(6) Issues

The appellant's statement of the issues in the brief is correct.

(7) Grouping of Claims

Appellant's brief includes a statement that the claims do not stand or fall together and provides reasons as set forth in 37 CFR 1.192(c)(7) and (c)(8).

(8) Claims Appealed

The copy of the appealed claims contained in the Appendix to the brief is still not correct for claim 5 and claim 9. Claims 5 and 9 as currently pending should read:

Claim 5. An assay device according to claim 9, additionally comprising a second population of said direct particulate label sensitised solely with said non-specific protein.

Claim 9. In an assay device wherein a sample liquid reconstitutes a labelled reagent and carries it into a detection zone and a control zone, binding of said labelled reagent in these zones revealing the assay result, the improvement wherein said labelled reagent comprises a particulate direct label co-sensitised with a first specific binding agent having specificity for an analyte, and (ii) a non-specific protein which can participate in a control reaction with another specific binding agent which does not bind to said first specific binding agent nor participate in the formation of a complex by means of which detection of said analyte is accomplished in said detection zone.

(9) Prior Art of Record

5,622,871	May et al	4-1997

(10) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claim Rejections - 35 USC § 112

Claims 2-11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

As to claim 9, and every claim dependent thereon (2-8, 10-11), the claims are indefinite because it is unclear if the claim is directed to an assay device, a process of assaying or the particulate reagent. The claim is further confusing because the prior claim required binding of the labeled reagent in a detection and control zone. Further the claim is not in compliance with 37 CFR § 1.75 (e), as in the case of an improvement, any independent claim should contain in the following order: (1) A preamble comprising a general description of all the elements or steps of the claimed combination which are conventional or known, (2) A phrase such as "wherein the improvement comprises," and (3) Those elements, steps, and/or relationships which constitute that portion of the claimed combination which the applicant considers as the new or improved portion.

As to claim 5, the claim is unclear because it is unclear if the recitation is "admitted prior art" as it relates to the preamble or is meant to reconstruct the direct particulate label of the Jepson claim (i.e. "said" direct particulate label).

As to claim 6, the claim is confusing because it is unclear what limitation is applied to what portion of particulate label of claim 9. The claims still lack proper antecedent basis. Applicants should restructure the claims to recite "wherein the particle of the direct label" is first colored latex particle of a diameter less than 0.5 micron, wherein the first specific binding agent is anti-hCG murine monoclonal antibody and wherein the non-specific protein is rabbit IgG. Clear relationships back to the independent claim is necessary to interpret the assay reagents of the Jepson claim format.

As to claim 7 and 8, it is unclear if the limitation is admitted prior art or not or how it limits the independent claim in a Jepson format. Again clear antecedent basis back to the independent claim is necessary. Is applicant intending to recite "wherein the labeled reagent additionally comprises a second latex particle of the same colour as the first latex

particle, wherein the second latex particle has a diameter of less than 0.5 microns and is sensitized solely with rabbit IgG and wherein the ratio of the first and second latex particles in the labeled regent is 2:1. Claim 8 as it depends from claim 7 is still unclear how it provides for clear antecedent basis in claim 8 and claim 7.

Claim Rejections - 35 U.S.C. § 102

Claims 5 and 9 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by May et al (U.S. Patent No. 5,622,871, filed July 15, 1993, issued April 22, 1997).

May et al teaches a particulate direct label co-sensitized with a first specific binding reagent having specificity for an analyte and a non-specific protein which can participate in a control reaction see column 16, lines 34-57, which teaches a coloured latex particle having an anti-alpha hCG antibody and bovine serum albumin co-sensitized on the direct particulate label and its use in a chromatographic assay (column 1, first full paragraph). May et al teach a device with the preamble elements and a coloured latex particle having an anti-alpha hCG antibody and bovine serum albumin co-sensitized on the direct particulate label and its use in a chromatographic assay (see the claims). As such, the prior art teaches the specific element that is defined by means of a Jepson claim to be the novel inventive contribution over the art. As such, any limitation that is not directed toward the labeled reagent comprising a particulate direct label co-sensitized with a first specific binding reagent having specificity for an analyte and a non-specific protein which "can" participate in a control reaction is not seen to limit the particular claimed device. There are no claimed structural elements that distinguish the device of the art from that of May et al. Further, the recitation of "can participate in a control reaction..." is not seen to distinguish the labeled particle of the prior art as compared to the claimed particulate direct label co-sensitized with two functional reagents. The "intended use" of the reagent in an assay does not limit the product "improvement" as is

now claimed in the newly recited Jepson claim format from a device having the same structural components.

(11) Response to Argument

Claims 2-11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

As to independent claim 9, the claims are indefinite because it is unclear if the claim is directed to an assay device, a process of assaying or the particulate reagent. Applicants argue that it is clear that Applicants are claiming an assay device because of the recitation of "The assay device" in the dependent claims. This is not persuasive the independent claim is a confusing recitation of process limitations "wherein a sample liquid reconstitutes"...and apparent products "wherein said labeled reagent". The skilled artisan must be able to ascertain a clear statutory of invention as it relates to a product, process of use or process of making. The independent claim itself does not make the statutory category clear and can not rely on other claims to provide for clarification or interpretation thereof. Additionally, the claims dependent from claim 9, do not, as applicants assert recite "The assay device". The issue with respect to "can" has been previously resolved in view of the Advisory Action of 10-3-03 and this aspect of the rejection is moot.

As to claim 9 and every claim dependent thereon, Applicants argue that the examiner is in error and the claims are in compliance with 37 CFR § 1.75(e). Applicants argue that the recitation of "the improvement wherein" is definite and meets the Jepsom claim format. This is not persuasive, the metes and bounds of the phrase is indefinite and does not follow the rule. The metes and bounds of the improvement is not set forth because there is no transitional phrase to indicate the scope of the improvement. This is not hypertechincal, the dependent claims must make it clear if the improvement is

amended or the preamble (as it relates to admitted prior art) is amended. These claims do not perform this function. This issue is further confused by the dependent claim 5, because it apparently recites an additional component and given the apparent Jepsom format of the claim it is unclear if this additional component relates to the preamble or the indefinite "improvement" or redefines (i.e. reconstructs) the direct particulate label as an improvement. It is unclear how the amendment relates to "said direct particulate label" of claim 9. The dependent claims do not take into account the apparent Jepsom format of the independent claim. Applicants indicate that they do not understand the rejection. The rejection reflects the lack of clarity of the claims as it relates to both the apparent Jepsom format of claiming and the "said direct particulate label" as set forth in the rejection of record. Applicants brief incorrectly recites the text of claim 5. Applicants arguments with respect to claim 5 are therefore moot. Applicants argue that no reasons for lack of antecedent basis are given. This is not true, the claim depends ~~form~~ from claim 2 and the antecedent basis and further limitations recited in claim 6 are it relates all the way back to claim 9 are unclear because it does not relate the recited anti-hCG and rabbit IgG with the specific recitations of elements using the language of either claim 2 or claim 9. Additionally, the examiner provided specific guidance for Appellants to resolve this issue as it applied to claims 6, 7 and 8. It is clear from the suggestion, what the problem was and how to resolve it. Applicants again complain about the lack of entry of the amendments. Again this is not an appealable issue. Applicants argue that the claims are clear when read in plain English. This is not persuasive, the amendments to dependent claims must make it clear if the preamble or improvement is amended. These claims do not make this clear. The preamble of the Jepsom claim is admitted prior art, the improvement defines what is new. When dependent claims neither clearly further limit the improvement nor specifically amend the preamble, it becomes unclear as to what Applicant's improvement really is. The fact that the examiner placed an interpretation on the claims for art purposes does not obviate the issue of clear antecedent basis and

~~weather~~ whether the dependent claims amend the preamble of the Jepson claim or the improvement recited therein. The position of the office is that the claims lack clarity, clear antecedent basis and it is unclear given the pseudo Jepson format crafted by Appellant whether the dependent claims constitute admitted prior art or are improvements *per se*.

For the foregoing reasons the rejections should be sustained.

Claims 5 and 9 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by May et al (U.S. Patent No. 5,622,871, filed July 15, 1993, issued April 22, 1997).

Applicants arguments regarding the limitation of the preamble in regard to the interpretation of art in the Jepson claim format is noted. Applicants argue that when the preamble is considered the art is not anticipatory. This is not persuasive. The claim as is reads on a device wherein a liquid sample reconstitutes a labeled reagent and carries it into a detection zone and control zone, the binding of said labeled reagent in the zones reveals the assay result. May et al does teach a device comprising the recited elements reciting a test zone and control zone wherein the test strip comprises a particulate direct label (see in particular claims 1, 8 and 9) released into mobile form by said applied liquid sample. It is unclear what aspect of the preamble that Appellant does not view as being taught by May et al. The examiner pointed to column 16 for the details of the claimed "improvement". Column 16 of May et al recites a direct particulate label for use in the test strip device wherein the direct particulate label comprises a coloured latex particle coated with an anti-alpha hCG antibody (i.e. the instant first specific binding agent having specificity for an analyte) and bovine serum albumin (i.e. a non-specific protein that does not bind to said first specific binding agent nor participate in the formation of a complex by means of which detection of said analyte is accomplished). All the elements of the claim are set forth by May et al. Appellants argue that the bovine serum albumin is merely a blocking agent and is not involved in any binding reaction in the device. This is not persuasive

because the control zone as set forth in the preamble does not define any specific binding partner or any reaction to take place. The particle on the test strip "can participate" is not in this case to be seen to be limiting when there is no structural element recited in the preamble that defines over the control zone of the prior art. Further, the control zone of the art provides a means for binding the labeled reagent and a reaction takes place therein. The claim does not require a control reaction to take place in the control zone, merely have some future potential as argued by Appellants. Appellants arguments with respect to claim 5 are not persuasive because they are directed to the incorrect form of the claim. The rejection is maintained over claim 5 in view of the lack of clarity and apparent redefinition of the direct particulate label. The rejection is withdrawn in view of the arguments with respect to claims 10 and 11.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,
Patricia A. Duffy

Primary Examiner

Art Unit 1645

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September 16, 2004

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